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Agricultural Biotechnology Annual

Spain's Annual Agricultural Biotechnology Report 2014

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Report Highlights:

Spain has an open approach to biotechnology and remains the European Union's (EU's) Member State with the largest area planted to GE crops. Field trials as well as confined research on genetically engineered (GE) plants and animals are permitted, although subject to prior notice and authorization. Regulatory constraints in the EU create an unattractive investment environment for seed companies and are negatively impacting the number of field trials being carried out. Spain's position on cultivation decisions has evolved throughout the years towards a more open approach in what we understand as an attempt to open the door to the cultivation of new events.

Disclaimer: Spain, as a member of the European Union (EU), conforms to EU directives and regulations on biotechnology. It is therefore recommended that this report be read in conjunction with the [EU-28 consolidated report](#).

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Acronyms used in this report:

- EC European Commission
- EU European Union
- FAS Foreign Agricultural Service
- MS Member State(s)
- MT Metric ton (1,000 kg)
- Ha Hectares
- GMO Genetically Modified Organism
- GE Genetically Engineered
- N/A Not available
- GTA Global Trade Atlas
- MAGRAMA Ministry of Agriculture, Food and Environment

Section I. Executive Summary:

Spain is the EU Member State with the largest area planted to Bt corn, representing about 90 percent of the EU total area. Spain has traditionally maintained a science-based and pragmatic approach to biotechnology with regards to cultivation and imports, which ultimately favors the competitiveness of its robust livestock sector.

Spain is a net importer of grains and oilseeds as domestic production is not sufficient to meet the demand of Spain's export-oriented livestock sector. Grain yields in Spain are closely related to the amount and timeliness of precipitation. Spanish grain imports vary from 9 to 12 million Metric Tons (MT), depending on the size of the domestic crop. Soybean and soybean imports combined amount to nearly 6 million MT.

Bulk commodities remain the U.S. largest agricultural exports product group to Spain. However, U.S. exports of bulk commodities vary significantly depending on competition of other origins.

MON810 corn has been commercially grown in Spain since 1998. Total area planted to corn varies every year based on water availability, irrigation costs, prices paid to farmers and competition from alternative crops. In 2014, a reduction in area planted corn is anticipated; hence, GE corn plantings projections are also expected to decline.

Spain's position on renationalization of cultivation decisions has evolved through the years towards a more open approach. Spain supported the current renationalization proposal in an attempt to move forward and open the door to cultivation of new events, provided that the role of European Food Safety Authority (EFSA) remains unchanged.

While field trials are allowed in Spain, they are subject to prior notice and authorization. Notifications to competent authorities for open field testing have significantly declined in the last five years, reflecting how regulatory constraints in the EU, which result in delayed approvals, create an unattractive investment environment for seed companies.

GE animal research abides by the same rules as GE plant research and it is also permitted, but subject to prior notice and authorization. To date, no notifications on confined research in animals have been publically released by competent authorities in 2014. However, it is our understanding that most of the notifications consist on basic science research for pharmaceutical purposes carried out by public institutions. There is no known research or development of GE animals for the food market in Spain.

As for cloned animals, there is no public register of research in cloning and notification on cloning research is not mandatory. According to media information, cloning is limited to research activities

focusing on endangered species, mice, hogs and fighting bulls, none of them intended for the food chain.

Section II: Plant and Animal Biotechnology

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Product Development

Both confined research and deliberate release to the environment is permitted in Spain although subject to prior notice, public information and authorization ([Law 9/2003](#)). However, other breeding techniques such as mutagenesis or marker assisted selection are not subject of authorization and do not need to be recorded. Despite the confined research and deliberate release carried out in the country, no new GE development is anticipated to be in the market within the next five years.

- **Confined Research:**

Confined research in Spain is permitted although subject to prior notice and authorization. Notifications to Spanish Competent Authorities in 2013 on confined research on GE plants included cotton and other not specified plant species. To date, no confined research in plants has been reported by competent authorities in 2014. However, it is our understanding that little research is carried out in the plant side. Most of the notifications consist on basic science research for pharmaceutical purposes carried out by public institutions.

- **Field testing:**

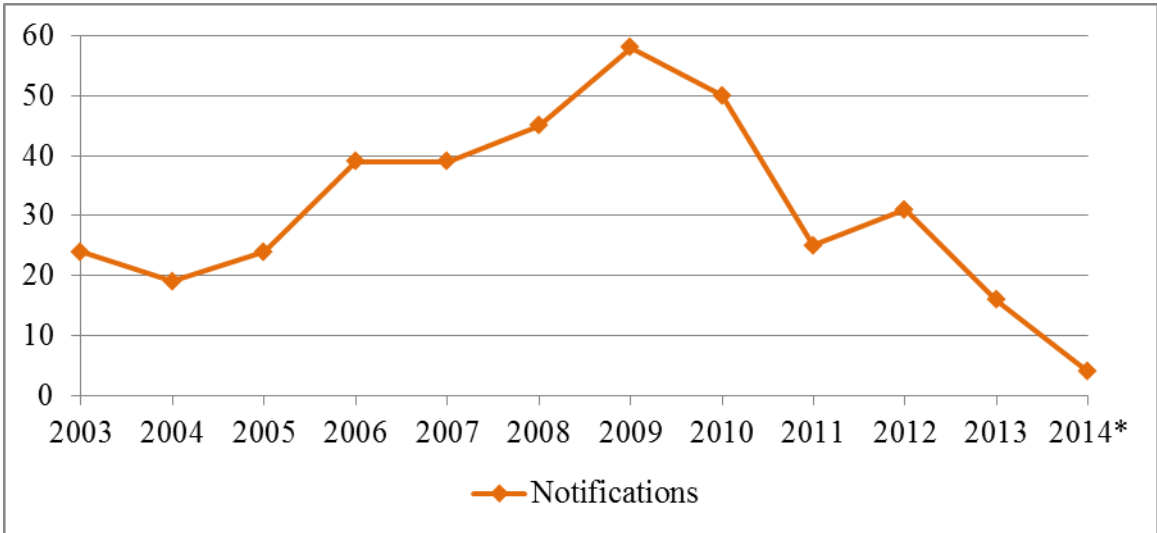
Field trials are permitted in Spain although they are subject to prior notice and authorization.

Notifications to Spain's competent authorities for deliberate release into the environment of GE products for other purposes than placing in the market in 2013 included: sugar beet (herbicide tolerant) cotton (for reference material production, insect protection and herbicide resistance traits) corn (insect protection and herbicide resistance traits, vitamin enriched corn and GE corn agro-ecosystems impact assessment) and wheat (with gliadins silenced). This GE wheat trial was approved by a [resolution](#) signed by the CIOMG in November 2013, following the CNB's [risk assessment](#) concluding that this release did not pose any significant risk for human health or the environment.

Notifications for deliberate release into the environment of genetically engineered plants for any other purposes than placing on the market for 2014 according to [JRC](#) (Joint Research Center) include corn (glyphosate tolerance, lepidoptera resistance, vitamin enriched endosperm) and potato (use of hexose phosphate transporter for production of potato plants with increased starch content) trials.

Notifications to competent authorities for open field testing have significantly declined in the last five years, after peaking in 2009. This reflects how private sector interest in developing GE crops adapted to Spain's conditions has waned. Regulatory constraints in the EU, which result in delayed approvals and uncertainty, create an unattractive investment environment for seed companies.

Table 1. Open Field Trials Notifications to Competent Authorities



Source: Foreign Agricultural Service (FAS) Madrid based on Joint Research Center Information.

**2014 data are based on data available up to May 31st 2014.*

b) Commercial Production

Spain is the largest EU producer of Bt corn representing about 90 percent of the EU's total area. MON810 corn has been commercially grown in Spain since 1998. Total area planted to corn varies every year based on water availability, irrigation costs prices paid to farmers and competition from alternative crops (**Table 1**). Production of GE corn is entirely used by the domestic feed industry.

Spain-based feed grain elevators do not keep separate lines for biotech and non-biotech corn as practically all marketed feed contains GE soybean as a source of protein, and consequently it is default labeled as "contains GE products".

The corn processing industry whose production is intended to enter the food chain (wet millers and dry millers) source its corn from GE free sources, in many cases under Identity Preserved (IP) programs.

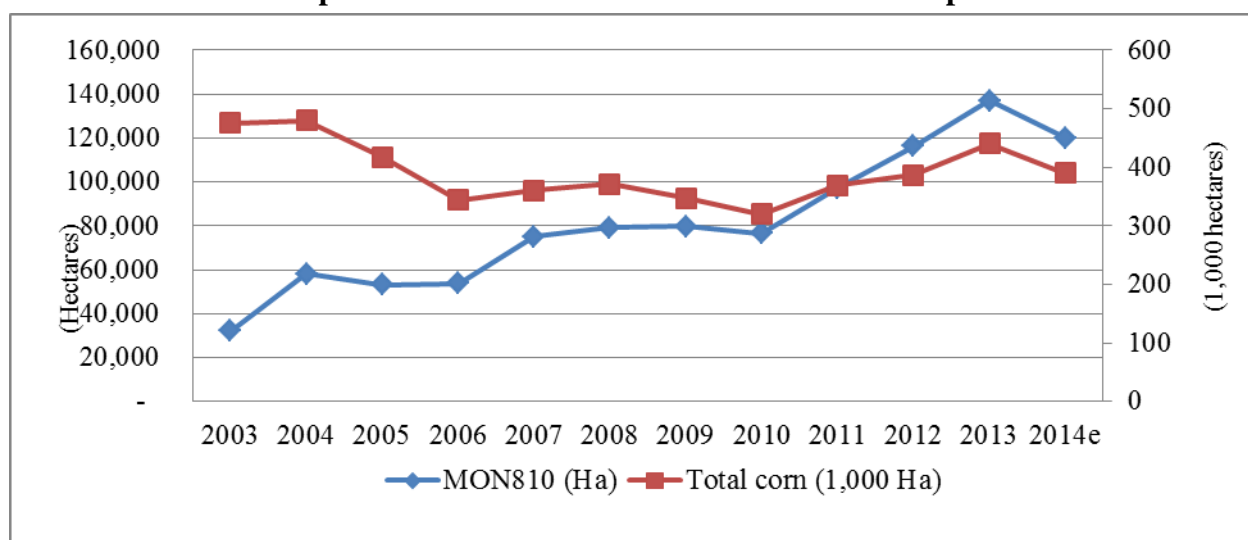
For dry milling, Argentina and the Black Sea Region are the main source of GE free corn, to some extent dry millers also source some GE free corn domestically. Wet millers source their corn from domestic producers that grow non-GE corn as well as from other EU origins (mainly France, but also from Bulgaria and Romania) and extra EU origins such as Ukraine, Argentina and Serbia.

Table 2. Spain's Corn Area and Production*

Marketing Year	MY2011/12	MY2012/13	MY2013/14	MY2014/15e
Area (1,000 Hectares [Ha])	370	387	441	390
Production (1,000 MT)	4,150	4,235	4,854	4,700

Source: MAGRAMA and FAS Madrid estimates. *Includes GE and not GE corn.

Graph 1. Total corn and MON 810 corn area on Spain



Source: FAS Madrid based on MAGRAMA data and FAS Madrid estimates¹.

Area planted to Bt corn continues to increase every year (**Graph 1** and **Table 3**) driven by an increased use of the technology that expanded to non-traditional areas and by an increase in overall corn plantings. The country's dependency on imported feedstuffs, the science-based approach to GE crops and the lower rejection to the technology than in lowering countries have contributed to the expansion of GE crops cultivation and imports over the years.

In 2013, an increase in total area planted to corn has resulted in record GE corn plantings in the Iberian Peninsula for the third consecutive year reaching 136,962 Ha. For more detailed information on 2013

¹ Since 2009, the Spanish Ministry of Agriculture, Food and Environment (MAGRAMA) publishes GE crop area including not only corn varieties in the national register in the EU common catalogue, but also those varieties granted with a provisional authorization. Figures from 2009 up to present in the chart above have been updated accordingly.

Bt corn record plantings see GAIN Report [SP1314](#). Information on previous records achieved in years 2011 and 2012 can be checked in GAIN reports [SP1119](#) and [SP1234](#) respectively.

However, in 2014 total corn area is expected to decline with farmers switching to alternative irrigated crops that depending on the region would consist on high quality wheat, sugar beet, tomatoes for processing or cotton. Latest official figures estimate area planted to corn in 2014 to amount to 428,000 Ha, however, based in the information provided by our contacts in the field, we believe that the overall grain corn area could be lower than that. Consequently the total area planted to GE corn would decline and GE corn plantings could amount to 120,000 Ha in 2014.

Table 3. Area of GE corn by Region (Hectares)

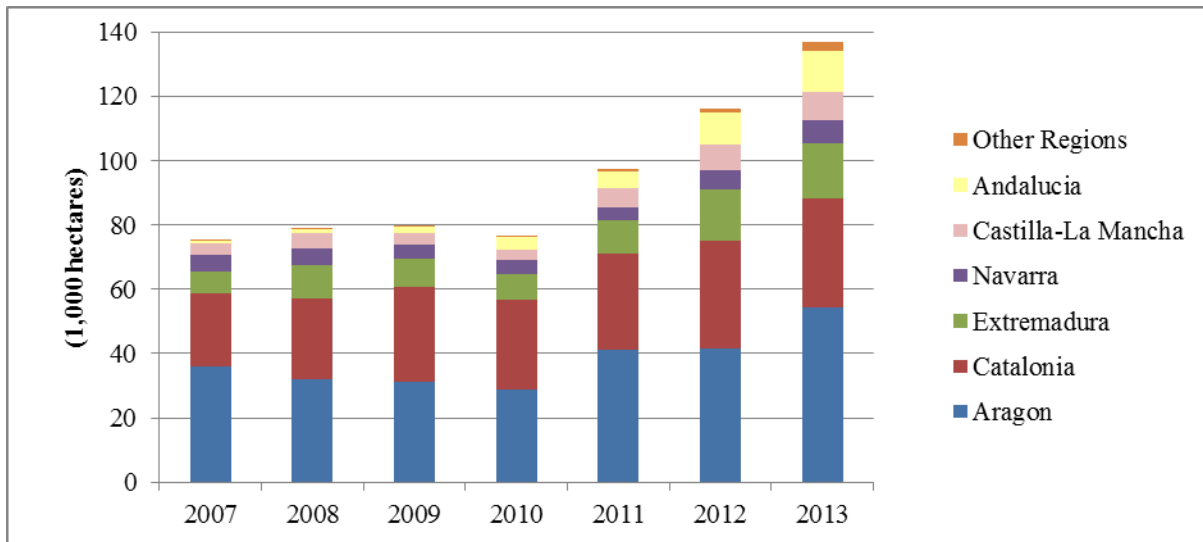
Region	2008	2009	2010	2011	2012	2013	2014e
Aragon	31,857	31,397	28,652	41,368	41,669	54,451	N/A
Catalonia	25,298	29,218	28,258	29,632	33,531	33,996	N/A
Extremadura	10,416	8,730	7,770	10,567	15,952	16,979	N/A
Navarra	5,150	4,691	4,477	4,096	5,801	7,013	N/A
Castile-La Mancha	4,739	3,417	3,187	5,817	7,883	8,766	N/A
Andalusia	1,372	2,084	3,773	5,244	10,362	12,862	N/A
Others	451	168	457	603	1,109	2,895	N/A
Total	79,283	79,705	76,574	97,326	116,307	136,962	120,000

Source: MAGRAMA and FAS estimates. (N/A = not available)

Final data for 2013 indicate that the Ebro River basin (autonomous regions of Aragon and Catalonia) concentrated the largest share of GE corn, 65 percent of Spain's total GE corn plantings. Of special interest is the GE corn area that took place in Andalucía, where Bt corn share has steadily increased over the last years (from 5 percent in 2011 to 9 percent in 2012 and 2013).

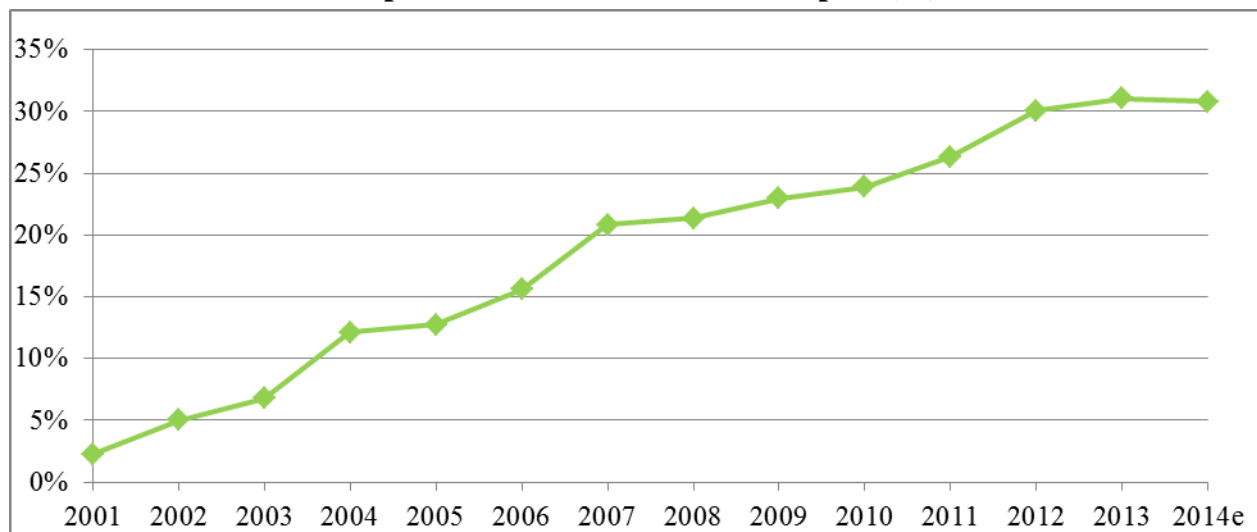
Since MON810 is the only GE event approved for cultivation, the possibilities of growth are limited to the size of the corn plantings in those areas where the corn borer represents a problem. Approvals of other events for cultivation could raise the interest for GE crops in other areas.

Graph 2. GE Corn Area by Region



Source: MAGRAMA.

Graph 3. MON 810 Area Share in Spain (%)



Source: FAS Madrid based on MAGRAMA data and FAS Madrid estimates.

c) GE crops exports

Spain is a net importer of grains and oilseeds as the domestic production is not sufficient to meet the demand of Spain's robust export oriented livestock sector. Hence, despite being the EU largest producer of biotech crops, GE product exports are negligible as production is used up by the domestic feed industry.

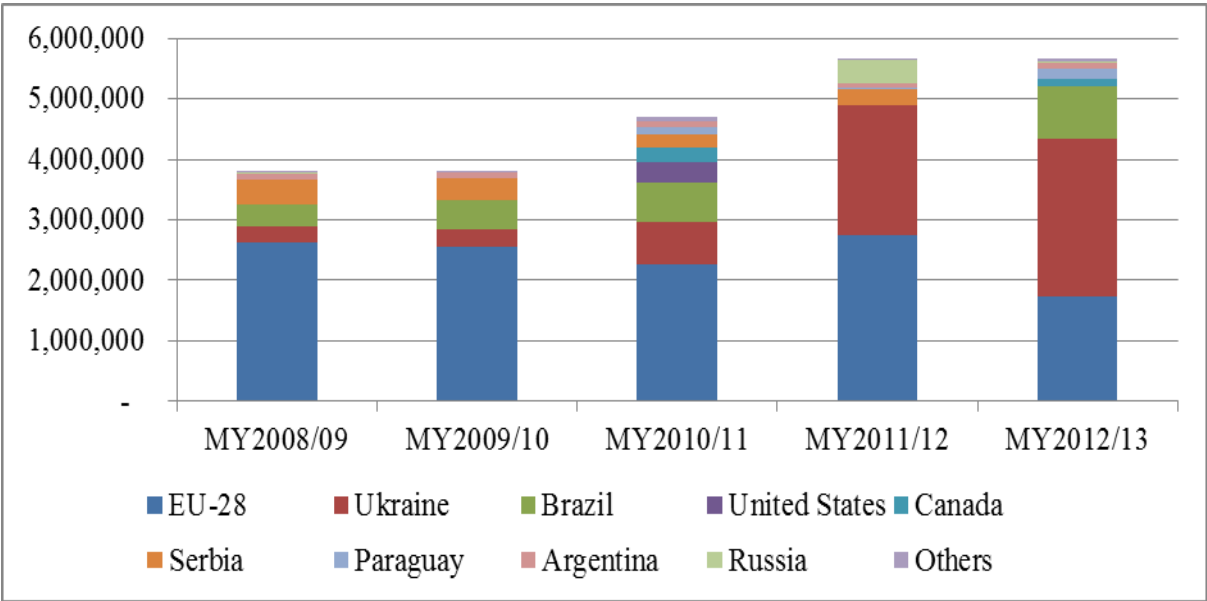
d) GE crops imports

Spain imports a large amount of GE crops and products. GE product imports to Spain consist mainly of soybeans originating in Brazil and the United States and soybean meal originating in Argentina to be processed by the Spain-based crushing and feed industries.

Spanish grain imports rank from 9 to 12 million MT and soybean and soybean meal imports combined amount to nearly 6 million MT.

Spain’s total corn imports have grown steadily over the last five marketing years due to increased competitiveness compared to other feed grains. While corn imports have grown, the United States corn share of imports is negligible due to the asynchronous approval of biotech events in the EU. Biotechnology adoption in Argentina and Brazil, who were also traditional corn suppliers to Spain, has forced Spain-based feedstuff importers to find alternative corn providers such as Ukraine, Serbia and Russia. Currently, intra EU trade and imports of Ukrainian corn supply the large majority of the Spain’s grain import market.

Graph 4. Spain’s Corn Imports (MT)*

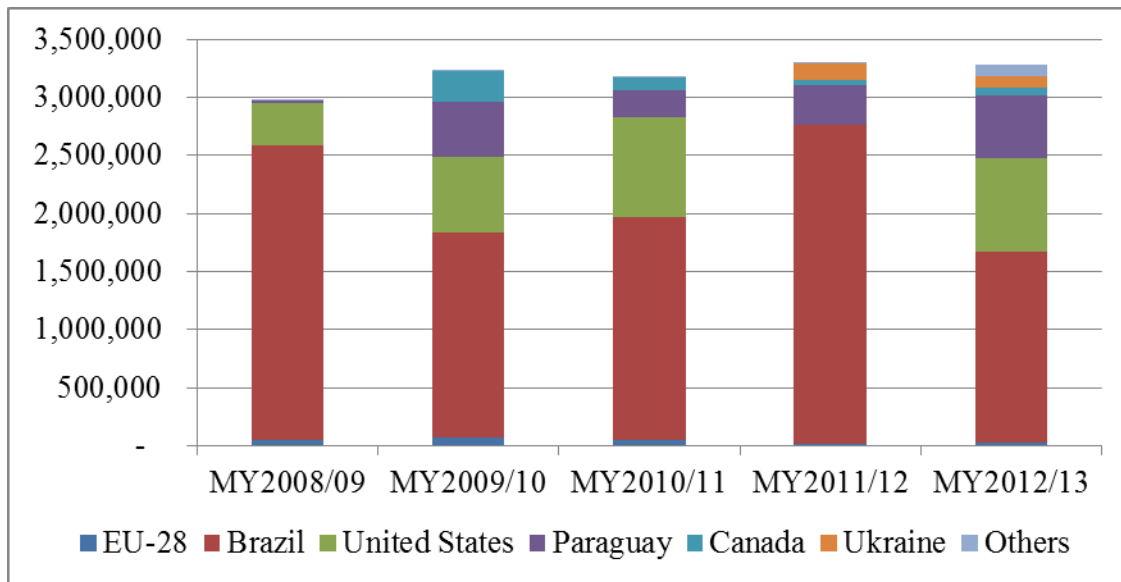


Source: Global Trade Atlas (GTA)

*Corn trade data are collected in Marketing Years basis. Corn MY runs October/September.

As it pertains to soybean and soybean products, the large majority of Spain’s imports are GE products. Virtually all of the soybean products imported to Spain are GE, with the exception of those devoted to special markets niches. Nevertheless, the impact of the slower pace of approval has been less significant in the protein feed ingredients than in the grain side. While Brazil and the United States supply most of the Spanish soybean market (See **Graph 5**), Argentina and Brazil combined supply the majority of the soybean meal import market (See **Graph 6**).

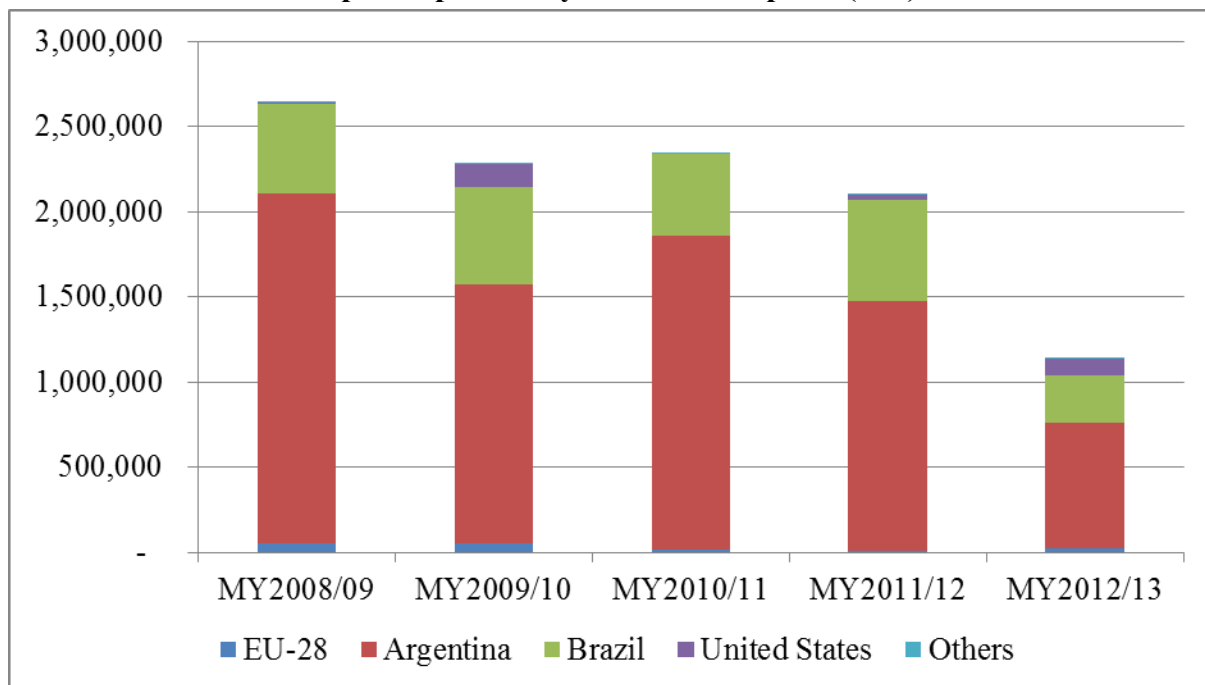
Graph 5. Spain's Soybean Imports (MT)*



Source: GTA.

*Soybean trade data are collected in Marketing Years basis. Soybean MY runs October/September.

Graph 6. Spain's Soybean Meal Imports (MT)*



Source: GTA.

*Soybean meal trade data are collected in Marketing Years basis. Soybean Seed MY runs October/September.

e) Food Aid Recipient Country

Not applicable.

Part B: Policy

a) Regulatory Framework

The EU's biotechnology policy agenda and rules are set in Brussels. As an EU Member State (MS) Spain must abide by EU rules, which in the case of Regulations are directly applicable to all EU MS. EU Directives need to be transposed into national laws, so they provide the opportunity for Member States governments to exercise some discretion without altering the basic scope of the EU directive. For more information on EU-28 Biotech Regulatory Framework please see [EU-28 report](#).

In the field of biotechnology, the EU [Directive 2001/18](#) on the deliberate release into the environment of genetically modified organisms was transposed to national regulation by [Law 9/2003](#) on confined use and voluntary release of genetically modified organisms.

This same piece of regulation created and defined the responsibilities of the two relevant authorities that weighed in on Spain's biotechnology decision making process, which are the National Biosafety Commission (CNB) and the Inter-ministerial Council for Genetically Modified Organisms (CIOMG). The CNB takes a scientific approach, whereas CIOMG's approach is technical.

At the national level, central and regional governments hold different responsibilities:

The central administration is responsible for:

- The marketing authorization for GMOs and products containing GMOs.
- Authorizing confined use and deliberate release of GMOs for research and development (carried out under national programs).
- Authorizing pharmaceutical products for humans or animals containing GMOs.
- Monitoring and control of field trials previous to the registration in the Commercial Varieties Catalogue.

The autonomous regions administrations are responsible for:

- Authorizing confined use and deliberate release of GMOs for research and development
- Monitoring and control of these activities, (with the exception of those belonging to the national government portfolio)

National Biosafety Commission (CNB)

The National Biosafety Commission is an advisory body whose role is to assess the requests for cultivation, confined use and marketing of GMOs submitted at either the national or regional level with a scientific approach. The CNB is comprised of representatives from different ministerial departments, representatives of the autonomous regions and experts in biotechnology. This Commission is chaired by the Director General of Environmental Quality and Assessment and Natural Environment. The composition of the CNB is available in the [link](#).

Inter-ministerial Council for GMOs (CIOMG)

The CIOMG takes a technical approach, and it is the competent authority to grant nationwide authorizations for confined use, voluntary release and marketing of Genetically Modified Organisms. The CIOMG coordinates its work with the CNB and liaises with the European Commission and the Autonomous Communities. This Council is chaired by the Secretary General for Agriculture and it is comprised by representatives of the Ministries that are somehow related to biotechnology. It includes representatives from the Ministry of Agriculture, Food and Environment (MAGRAMA), the Ministry of Health, Social Services and Gender Equality (MSSSI), Minister for Economic Affairs and Competitiveness (MINECO) and the Ministry of Internal Affairs (MIR). The composition of the CIOMG is available in the [link](#).

Other Ministerial departments involved

The Spanish Office of Vegetal Varieties, belonging to the Directorate General for Agricultural Productions and Markets, is responsible for registering and monitoring of GE seed for planting. Information on the corn varieties registered for planting in Spain is available in the [link](#). At present there are over 120 GE corn varieties approved for commercial cultivation.

Within the MAGRAMA, the Sub directorate General for Animal Feed and Resources Preservation coordinates the National plan in feedstuffs whereas AECOSAN², the Spanish Consumption, Food Safety and Nutrition Agency, ascribed to the Ministry of Health, Social Services and Equality is in charge of the food chain control.

Other non above listed Ministerial Departments weigh in to the GE decision process through their participation in the Inter-ministerial Council for GMOs (CIOGM) or the National Biosafety Commission (CNB).

² In February 2014, by the publication of [Royal Decree 19/2014](#) the National Institute for Consumption merged with the Spanish Food Safety and Nutrition Agency to and become AECOSAN, the Spanish Consumption, Food Safety and Nutrition Agency.

Civil Society Participation - Consultative Committee for GMO

While the cultivation of GE crops is permitted, Spain is also strengthening public information and participation. The Consultative Committee for GMO (CPOGM) ascribed to the Inter-Ministerial Council was created in October 2010 by [Ministerial Order 2616/2010](#). This body's main objective is to reassure public participation in GMO issues so that the Inter-Ministerial Council obtains first-hand information of civil society representatives. The CPOGM can express its opinion on decisions to be taken and it is entitled to prepare proposals to be examined by the CIOMG. The CPOGM is comprised by representatives of farmers' unions, agricultural cooperatives, consumers' organizations, labor unions, conservation NGOs, food industry, pharmaceutical industry, the entrepreneurial organization and the national network for rural development. The seed breeding industry is not represented in this consultative group.

b) Approvals

- For imports:

Approvals of events for imports are dealt with at the EU level. Please see the [EU-28 Biotechnology Report](#) for a list of approved GE events.

Member States have the chance to weigh in in the approval process through their participation in the EU committees, both at the technical and political level. For more information on the EU approval process, please see [EU-28 Biotechnology Report](#).

With only a couple of exceptions, Spain has traditionally voted in favor of new events for imports in the Standing Committee on the Food Chain and Animal Health in Brussels.

Spain has a two-tier system for the national decision making process to come up with the country's position:

- The CNB carries out the risk assessment
 - The CIOMG decides the country's position taking into consideration CNB assessment.
- For cultivation: (more detailed information available in the **Trade Barriers** Section)

Spain's position on renationalization of cultivation decisions has evolved through the years. When the debate on renationalization of cultivation decisions was first launched, Spain reacted cautiously putting forward concerns over common market implications and WTO rules compliance.

However, in more recent occasions (Council of Ministers of Environment held on March 2014) Spain has expressed a more open approach to the renationalization of cultivation decisions in what we understand as an attempt to open the door to cultivation of new events, provided that the role of EFSA remains unchanged.

c) Field testing

Field trials are permitted, although subject to prior notice. (More information in **Part A: Production and Trade: Product Development**)

d) Stacked Events Approvals:

See section c) on approvals as the procedure in place is the same for single and for stacked events.

e) Additional Requirements: GE Crops Field Register

While it has been largely debated in the past, at the moment, there is no commercial GE fields register regulation enforced in Spain. The Spanish agricultural administration is reluctant to publish commercial GE crops plots location as a full disclosure of GE crops plot location, which could be misused. The only information publically available about commercial GE crops plantings in Spain is the total area at the province, regional and national level that is calculated based on GE seed sales records and it is publicly available at the Ministry of Agriculture, Food and Environment [website](#).

f) Coexistence

Despite being the EU's largest GE crop grower, Spain has not implemented a coexistence regulation.

A first draft of a coexistence decree was made public in 2004 but abandoned due to the lack of consensus among the interested parties. Despite the lack of coexistence measures, Spanish farmers continue to grow biotech corn without any incident between farmers.

The Spanish agricultural administration would prefer clearer EU wide rules to develop coexistence plans to be provided by the European Commission, as opposed to national measures.

At present, coexistence in Spain is managed by following the [good agriculture practices](#) promoted by ANOVE, the National Association of Seed Breeders, which is published on a yearly basis and handed out along with seeds by the seeds distributors.

g) Labeling

Spain follows EU-harmonized legislation on labeling ([Regulation European Commission \(EC\) 1829/2003](#) on Genetically Modified Food and Feed, and [Regulation \(EC\) 1830/2003](#) on the Traceability and Labeling of Genetically Modified Organisms) and there is not any non-biotech labeling regulation developed at the national level.

The EU food labeling regulations provide for a 0.9 percent threshold for the "adventitious", that is, accidental and technically unavoidable, presence of EU-authorized biotech event in a non-biotech food or feed. Food or Feed products containing amounts above 0.9 percent must be labeled as "Contains Genetically Modified Organisms".

Bt corn planted and harvested in Spain is mainly utilized for the production of domestic compound feed, which is by default labeled as containing "Genetically Modified Organisms" since the large majority of the soybean meal used in feed production is GE.

On the contrary, the large majority of food manufacturers have eliminated biotech products from food product composition to avoid labeling as "Contains GMOs".

More detailed information on the EU-harmonized labeling legislation is available in the [EU-28 FAIRS Report](#) well as the [USEU website section on labeling](#).

h) Trade Barriers

- Asynchronous approvals:

The asynchronous approval of events cultivated in the United States and not authorized for imports in the EU-28 remain the main trade barrier. The beginning of GE corn plantings in the United States caused a drastic decline in United States corn imports to Spain. Depending on the size of the domestic crop, Spain needs to import between 9 and 12 million MT of grains. The expansion of GE crops in traditional grain suppliers to Spain has had a significant impact on trade flows. Ukraine, Serbia and Russia have progressively increased their market quota over the years at the expenses of lower imports from the United States, Argentina and Brazil.

- GE-free Zones:

Aside from the commercial production and research areas for GE crops, some Spanish municipalities/provinces have declared themselves GE free zones. These zones are created by political declaration at the municipality, province or regional level. Most of these areas are located in regions where the type of agricultural production cannot benefit from the current GE events available for

cultivation in the EU. It is our understanding that there is no legal enforcement mechanism connected to this declaration that would prevent a farmer from growing GE plants in these zones.

- Renationalization of cultivation decisions:

The debate in regards to the renationalization of cultivation decision was first launched back in 2010, when Spain reacted cautiously. At that time, Spain's main concerns regarding cultivation opt out, were the compatibility with the common internal market and the compliance with WTO rules.

Spain's position on renationalization of cultivation decisions has evolved through the years towards a more open approach in what we understand as an attempt to move forward and open the door to cultivation of new events. It is our understanding that Spain defends that the role of EFSA should not be questioned. Hence, once EFSA has published a positive assessment of a new GE crop, seed companies would launch conversations through the European Commission with the different Member States and the GE crop would only be authorized in those countries that have expressed an interest in the new GE crop.

Nevertheless, some sources fear that the renationalization of the cultivation decisions might lead to an internal regionalization, which is particularly worrisome in Spain, a country comprised by 17 Autonomous Regions with very diverse agronomic conditions.

i) Intellectual Property Rights (IPR)

The Community Plant Variety Right (CPVR), issued by the Community Plant Variety Office ([CPVO](#)) in Angers, (France), provides intellectual property rights for protection of plant varieties. However, the European Patent Convention (EPC) of October 1973 excludes patents for plant varieties. The CPVR enables breeders to be granted a single intellectual property right operative across the EU. The CPVR coexists with individual Member States' national plant protection legislation as an alternative form of protection.

Spain has its own Plant Varieties Protection System although harmonized with the EU regulations so that Common Market rules are observed. Plant Varieties Protection Rights are regulated by [Law 3/2000](#) that harmonizes Spanish legislation with EU Regulation and the Union for the Protection of New Varieties of Seeds (UPOV) rules.

Within the Ministry of Agriculture, Food and Environment, the Spanish Office for Plant Varieties (OEVV) manages import requirements, seed registration and certification, and commercial seed catalogs for planting seeds and nursery products.

Spain has a two-step registration process. The OEVV manages a National Catalogue of Commercial Varieties that can be freely marketed in the country and a National Catalogue of Protected Varieties. This system allows breeders to assess varieties potential and to get farmer's feedback before incurring in the further costs implied in the protected varieties registration.

- The Register of Commercial Varieties enables to start reproducing and commercializing plant varieties in Spain.
- Register of Protected Varieties enables the owner to collect property rights and the carry out the exclusive exploitation of a plant variety Spain.

An application form has to be presented for new plant varieties to be registered in the Commercial Varieties Catalog. Prior to their registration in the Commercial Varieties Catalog the new varieties are tested to verify that they meet the condition of being different, homogeneous and stable.

The registration in the Protected Plant Varieties Catalog is voluntary. The Spanish law on Plant Varieties Protection Rights intends enhance of breeders' rights providing varieties in the Protected Plant Varieties Catalog with a 25 years protection period.

It is not possible to hold protection for the same plant variety under both the Community and a national system at the same time. When a variety is granted with the CPVR the breeder has to choose whether to keep the national or the European right. GE seed breeders opt for the Community protection over the national protection.

MON810 is the only biotech event commercially grown in Spain and, as most of the corn cultivated in Spain, including GE varieties, it is a hybrid. IPR is not an issue for Spain's GE crops as hybrid seeds are not replanted.

j) Cartagena Protocol Ratification

The EU is a signatory to the Cartagena's Biosafety Protocol (Protocol), and so is Spain as a Member State of the European Union. Spain adhered to the Protocol on January 2002.

At the national level, the Protocol is followed by the Ministry of Agriculture, Food and Environment and in particular, the Support Unit within Directorate General for Agricultural Production and Markets (protocolo.cartagena@magrama.es). Spain regularly attends to the Cartagena Protocol Meeting of Parties.

Additional information on the Cartagena's Biosafety Protocol can be found in its [official website](#).

k) International Treaties and Fora

Spain's participation in international treaties and fora is not different from that of the EU. For more information on this regard it is recommended to read the [Consolidated EU-28 Biotechnology Report](#).

l) Related issues: N/A

There is little official information on new breeding techniques being utilized in Spain, as techniques such as mutagenesis or marker assisted selection are not subject of notification or authorization and do not need to be recorded.

m) Monitoring and testing

Spain monitoring and testing system is based on EU set rules. However, due to the country decentralized structure, testing and controlling are carried out at the regional level, while central government has the authority over customs.

The Autonomous Regions establish their own monitoring and sampling plans throughout the food and feed chain coordinated by national authorities. Sampling plans are based on risk assessment and it is primarily done at the wholesale and the processing level.

Spain uses the [Rapid Alert System for Food and Feed \(RASFF\) database](#) to report food safety issues to consumers, the trade, and other member-states. No shipments were rejected in 2013 due to presence of unauthorized genetically modified products. To date, only three shipments originated in China have been rejected in 2014 due to unauthorized presence of GE products in Spanish Border Inspection Points.

n) Low Level Presence

As a member of the EU, Spain conforms to EU directives and follows EU regulations on biotechnology. Since July 2011 the EU legislation sets at 0.1 percent³ the 'technical zero' level for shipments devoted to the **feed** market.

However, for products that will enter the **food** chain the tolerance is zero. As a consequence, adventitious presence continues to be a concern for traders, who carry out a no-risk policy in their purchases, regardless the final use.

³ *This level corresponds to the lowest level of GE material taken into account by the EU reference laboratory for the validation of quantitative methods. It is only applicable to "adventitious" presence in feed material of non-approved GMOs for which an authorization procedure is pending in the EU or for which an authorization has expired.*

The Spanish food industry would support an LLP solution for food. At the government level, Spain's position is decided through the Inter-Ministerial Council for GMOs (CIOMG), which puts together representatives of each Ministry implied in the regulation of agricultural biotechnology (See **Regulatory Framework** Section). However, in those matters affecting directly consumers like LLP for food, AECOSAN, the Spanish Consumption Food Safety and Nutrition Agency ascribed to the Ministry of Health whose constituents are consumers, plays a bigger role in the Council decisions.

In the case of **seeds**, a threshold level for adventitious GE material presence has not yet been set. As a consequence, Spain is forced to source its GE seeds from a limited number of origins (South Africa and domestically produced seeds). The domestic seed breeding industry continues to request the definition of a threshold limit of adventitious presence in seeds to open the trade to other seeds producers.

As the cultivation of GE crops outside the EU continues to grow and so does seeds trade, the Spanish seed industry would benefit by setting clear rules in regards to adventitious presence of GE seeds in conventional seed lots and define EU-wide threshold levels for labeling prior to any other regulatory development.

Part C: Marketing

a) Market Acceptance

The presence of GE labeled consumer-oriented products is very limited in the Spanish market. The large majority of food manufacturers have eliminated biotech products from food product composition to avoid labeling as "Contains GMOs".

On the contrary, the large majority of livestock breeders use compound feed labeled as containing "Genetically Modified Organisms" and the GE-free feed market niche is rather small.

Meat obtained from animals fed with GE feed does not have to be labeled so end consumers cannot show a preference in their meat purchases.

b) Public/Private Opinions

Spain's government has traditionally taken a pragmatic and science-based approach to the biotech regulatory process. Spain works hard to ensure that science is an important ingredient in the decision making process. Spain defends the role of the European Scientific institutions.

Within the agricultural sector, biotechnology is perceived as a tool to improve the competitiveness of farms through higher yields and lower input use. The use of biotechnology is also considered beneficial for the agro-food sector as a whole given the country's dependency on imported raw materials. The large majority of Spain's farmers associations are in favor of planting biotech crops. The use of agricultural technologies such as biotechnology or irrigation systems to improve competitiveness and obtain consistent output levels are positively perceived and defended by a large majority of the farming sector. However, as the number of biotech crops approved for cultivation in the EU at the moment comes down to Bt corn, not all farmers are directly benefited by the use of biotechnology. New approvals of other events that address issues affecting different crops, areas or oriented to consumers benefits would contribute to raise more interest among other growers, regions or consumers.

The Spanish feed and livestock industries have been traditional supporters of agricultural biotechnology. Spain boast of one of the EU largest livestock sector and, in the case of the pig sector, exports nearly one third of the production to EU and third markets. Consequently, given that livestock producers face global competition and Spain's dependency on imported feedstuffs, Spain feed and livestock industry have claimed in numerous occasions an increased access to biotech products in order to compete in equal conditions in the world markets.

There is not a strong reaction from retailers or meat consumers in Spain.

c) Marketing Studies:

There are not many recent country-specific studies on marketing or acceptance of biotechnology in Spain.

In regards to public perceptions on biotechnology, Eurobarometer 2010 concluded that Spain's index of optimism for biotechnology/genetic engineering was among the highest within the EU (74 percent) and so is Spain's support for GE food (35 percent of respondents agreed or totally agreed that GE food should be encouraged).

In a [Eurobarometer survey](#) carried out in 2011 regarding environmental issues that worried citizens, Spanish citizens showed less concern over the use of GE crops than the EU average (13 percent versus 19% of the Europeans). Moreover, Spaniards were far more concern about agricultural pollution originated by the use of fertilizers and pesticides (26 percent compared to 25 percent of the Europeans).

In a more recent study (August 2013) carried out by the Food and Resource Economics Department from the University of Florida [comparing perceptions of biotechnology in fresh versus processed food](#) Spain was categorized as a country with low-rejection of biotech food. The study also stated that respondents in Spain showed optimistic attitudes of biotech benefits and a high proportion of them were assigned to a GE tolerant cluster. The University of Florida study concludes that the

benefit that respondents in Spain valued the most was the reduction of pesticide use that biotechnology allowed.

Regarding GE crops production benefits, a study on “[*How can specific market demand for non-GM maize affect the profitability of Bt and conventional maize? A case study for the middle Ebro Valley, Spain*](#)” published in 2012 by the Spanish Journal to Agricultural Science, a publication managed by INIA (Spanish Public Agricultural Research Institute), concluded that the use of Bt corn in Spain increases farmers’ partial gross margins ⁴by 95 Euros per hectare on average.

Another study published in November 2013, entitled “[*15 years of Bt maize cultivation in Spain: Economic, social and environmental benefits*](#)” and founded by the Antama Foundation⁵, highlighted how the cultivation of Bt corn in Spain since has reduced total corn imports by more than 853,000 MT.

Part D: Capacity Building and Outreach

a) Activities

FAS Madrid has not carried out any capacity building or outreach activity using USDA funds.

FAS Madrid continues maintaining and sharing information available on biotech related issues with key stakeholders, serving as a source of reliable information.

FAS Madrid engages with host country officials during the EU decision making process or EU directive transposal into national law to inform on key technical issues, U.S. position and potential trade implications trying to contribute to the elaboration of rational policies that do not undermine Spain and United States common interests.

b) Strategies and Needs:

N/A

⁴ In the study “Partial gross margin” is defined as the difference between farmer’s income and those variable costs which may be different in Bt and conventional maize production (i.e. seed and pesticide costs). Other variable costs not affected by the choice of Bt or conventional maize production were not included in the partial gross margin analysis (i.e. costs which may not be different between both crops, such as herbicide treatments, fertilizers and energy and water use).

⁵ Fundacion Antama is a non-profit organization that promotes awareness of new technologies applied to agriculture. The Foundation is supported by the seed companies based in Spain and institutions in favor of agricultural biotechnology.

Chapter 2: Animal Biotechnology

Under Animal Biotechnology, Animal Genetic Engineering and Animal Cloning are included. While Animal Genetic Engineering implies modification of the animal's DNA, animal cloning is a type of assisted reproduction which does not modify the animal's DNA but, on the contrary it can contribute to preserve valuable genetic characteristics of livestock animals or endangered species.

Part E: Production and Trade

a) Product Development

There is no known research or development of GE animals intended for the food market in Spain.

Research conducted using **animal biotechnology** is permitted although it is subject to prior notice through the same procedure and institutions as plant biotechnology. According to the public log managed by the Spanish Ministry of Agriculture, Food and Environment, notifications of confined research on GE animals throughout 2013 was carried out with mice for medical purposes. To date, no confined research in plants has been reported by competent authorities in 2014. However, it is our understanding that most of the notifications consist on basic science research for pharmaceutical purposes carried out by public institutions.

Of particular interest is an authorization request presented in 2013 for the deliberate release to the environment of GE olive flies in Spain. The request, addressed to the Regional Government of Catalonia, was withdrawn later in the year by the same company that presented it.

As for **cloned animals**, in Spain, Somatic Cell Nuclear Transfer (SCNT) has occurred since 2003. Currently, public research centers and universities are trying to learn and improve the technology. No private companies are involved so far in this kind of research.

There is no public register of research in cloning and notification on cloning research is not mandatory. According to information provided by media, cloning is limited to research activities and attempts include so far:

- Wild goat by Scientifics from the Centre of Research and Agro-food Technology of Aragon (CITA) along with colleagues from the National Research Institute of Agriculture in Madrid (INIA) in 2003.

- Cloned mice by a public institution (Department of Cell Biology, Physiology and Immunology at the Autonomous University of Barcelona (UAB) in 2009.
- Cloned swine by the Department of Animal reproduction at the Murcia University in 2009
- Cloned bullfighting bull by researchers at Valencia's foundation for Veterinarian Investigation along with the Center for Investigation Prince Felipe in Valencia in 2010. Reportedly, this bull did not present the original bull's desired behavior and was dismissed from breeding purposes.

b) Commercial Production

There are neither GE animals nor cloned animals commercially used in Spain. There is no production of GE animals or clones intended for the food market in Spain. GE animals in Spain are authorized for research purposes.

c) Exports:

Spain does not produce commercial **GE animals, clones** or products; hence there are no known exports within these categories.

d) Imports:

GE animals have been imported to Spain for research purposes. GE animal imports are subject of notification to customs authorities.

On the contrary, as information on whether embryos or semen is sourced from a **cloned animal** is not included in the import documents, Spanish livestock industry may have imported semen and embryos from cloned animals, without this information being recorded.

Part F: Policy

a) Regulation

GE animals are ruled by the same authorities as GE crops and notifications for confined use or release to the environment are regulated by the same provisions (See **Chapter 1. Part B: Policy. Regulatory Framework**). In addition to that, specific regulations for animal research were introduced by [Royal Decree 53/2013](#).

In regards to **cloning**, there are two ministerial departments that are involved in the position definition: the Ministry of Agriculture, Food and Environment and the Ministry of Health.

Within the Ministry of Agriculture, Food and Environment, the Sub directorate General for Livestock Resources coordinates this issue and it has a technical approach to cloning as a breeding technology, while the Sub directorate General for Animal Health watches animal welfare implications. Also the Sub Directorate General for Sanitary Agreements and Border Control would have a role in enforcement if restrictions to trade were to be implemented.

Additionally, AECOSAN (Spanish Consumption, Food Safety and Nutrition Agency) an independent agency ascribed to the Ministry of Health, whose constituents are consumers, is invited to weigh in food risk related aspects.

Implementation of EU directives/ Country specific perspectives/country specific legislation

Domestic regulation applicable to GE plants also applies to GE animals. Spain has not specifically regulated GE animals or clones. With regards to cloning, national authorities launched an internal debate after two proposals prepared by the Commission were released⁶. To date, the country's final position is yet to be decided. However, it is our understanding that Spain will continue to defend a science-based approach in the decision making process.

b) Labeling and Traceability:

Spain has implemented EU legislation on labeling and traceability. For more information on this regard it is recommended to read the [Consolidated EU-28 Biotechnology Report](#).

c) Trade Barriers

At the moment, there are no known trade barriers related to GE or cloned animals.

d) Intellectual Property Rights

Spain has implemented EU legislation. For more information on this regard it is recommended to read the [Consolidated EU-28 Biotechnology Report](#).

e) International Treaties/Fora

Spain's participation in international treaties and fora is not different from that of the EU. For more information on this regard it is recommended to read the [Consolidated EU-28 Biotechnology Report](#).

⁶ A [proposal on the placing on the market of food from animal clones](#) and a [proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes](#).

Part G: Marketing

a) Market acceptance

At the consumer level, cloning or GE animals are not widely discussed. The use of animals for medical research aimed at finding cures for diseases is generally regarded favorably. EU wide and Member States specific perceptions in regards to animal cloning can be found in the 2008 Eurobarometer Report [“Europeans’ attitudes towards animal cloning”](#)

b) Public/Private Opinions

Spain is a country with a robust livestock sector and pragmatic in regards to the use of new technologies in the field of agriculture. Similarly to the situation in other countries, while the technical experts understand the technology and defend a science-based approach, fears about public opinion still have high specific weight in the decision making process.

Spanish livestock breeding interest has showed a limited interest in cloning so far due to the high costs implied. Additionally, while the conservation of positive productive traits is considered beneficial, the erosion of biodiversity is considered as a bottle neck for this technology.

f) Market studies: N/A

Part H: Capacity Building and Outreach

a) Activities:

In September 2013, FAS Madrid hosted the visit FAS Senior Science Advisor for animal biotechnologies. During this visit an open exchange of information took place between Spanish industry and technical expert on the issue. While cloning was the primary target of the visit, the use of new technologies in agriculture such as biotechnology was also tackled.

b) Strategies and needs:

N/A

Related Reports

Report Title	Date Released
<u>Spain Continues Expansion of GE Corn Plantings</u>	09/25/2013
<u>Agriculture Biotechnology Annual 2013– EU-27</u>	09/10/2013
<u>Agriculture Biotechnology Annual 2013 – Spain</u>	07/10/2013
<u>MON810 Corn Area Hits New Record in the Iberian Peninsula</u>	10/08/2012
<u>MON810 Corn Area Reaches Record Level on the Iberian Peninsula</u>	10/06/2011